EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-02

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Toxcast Data Release Workshops
	Base Option Period Number 1	

Contractor	Specify Section and paragraph of Contract SOW
ICF Incorporated, L.L.C.	E. Risk Assessment Support

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
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Authorized Work Assignment Ceiling

Contract Period:	Cost/Fee:	LOE:
11/01/2013 To 10/31/2015		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Monica Linnenbrink (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-1522 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1--02 PWS

Title: Toxcast Data Release Workshops and Data Summit

PERIOD OF PERFORMANCE: November 1st, 2014 – October 31, 2015

Specify Section & Paragraph SOW: E. Risk Assessment Support

I. PURPOSE:

This work assignment is a follow-on to work performed in the Base Period under Work Assignment #0-02. The purpose of the work assignment is to provide continued services to the U.S. Environmental Protection Agency's (EPA) Immediate Office of the Assistant Administrator (IOAA), Office of Research and Development (ORD), in the completion of providing administrative and logistical/facilitation support services for the Toxcast Data Summit that occurred on September 29-30, 2014. Two other toxcast data release workshops were completed during the base period of the contract. This work assignment is consistent with the purpose and scope of Contract EP-C-14-001.

II. BACKGROUND:

Recent advances in chemical safety research provide innovative solutions to persistent and pervasive issues facing risk assessments and policy decisions made about the safety of chemicals. To address some of these issues, EPA's chemical safety research has been using advances in computational toxicology to begin addressing the significant lack of health and environmental data on the thousands of chemicals. This computational toxicology research integrates advances in molecular biology, chemistry, toxicology, exposure science and computer science to more effectively and efficiently rank chemicals for potential risk.

Since 2005, EPA researchers have generated massive amounts of hazard data on thousands chemicals, designed innovative chemical exposure prediction models and created a repository of thousands of high quality chemical structure data. Using advances in computer science, these data sources can be searched and queried together to help predict the potential risks of chemicals to human health. Policy makers and stakeholders can access this data and developed models to help inform decisions they make about chemicals. However, because the chemical data is so massive and new, there are data translation, accessibility and usage challenges. These challenges can begin to be addressed by implementing outreach and engagement activities targeting stakeholder groups. One outreach strategy EPA plans to use to help with data translation, accessibility and usability challenges are face-to-face workshops for external stakeholders who have an interest in using this new data to inform decisions made about chemical safety.

III. STATEMENT OF WORK:

A. Objective:

The overall objective of this work assignment (WA) is to provide administrative and logistical support for a series of three (3) meetings in the form of two workshops and a Data Summit meeting. Support included

planning for meeting and logistics, onsite meeting support and facilitation, a summary report (including meeting and breakout discussion notes), communication activities related to the meeting and coordinating an evaluation mechanism to solicit feedback from workshop participants. The Data Summit was previously rescheduled from May, 2014 and was held September 29-30, 2014 in Research Triangle Park, NC and had over 200 participants. This work assignment is to provide post-meeting support necessary to closeout this effort. Administrative support shall consist of the following task:

B. Specific Requirements (Tasks):

1. Post-Meeting Support and Reporting

- Provide post-meeting summary report for the Toxcast Data Summit in similar format to previous summary report for stakeholder workshops including;
    - notes captured during the discussion at the plenary sessions and breakout groups. The notes should highlight key decisions and action items.
    - updated attendees list (including walk-ins).
    - data summit surveys from participants.

- Post all presentation materials on event web site.

IV. SCHEDULE OF DELIVERABLES

The following table provides a complete list of required work assignment tasks that are to be completed as part of this contract.

Work Assignment Task	Required Completion Date
Post electronic version of presentation materials, and any materials submitted by presenters following the meeting to the event web site.	Fourteen working days following Data Summit.
Complete and submit post-Data Summit final report	To be completed by November 14, 2014.

V. Notice Regarding Guidance Provided Under this Project

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

VI. Special Conditions and Assumptions

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a weekly update to the WAM by telephone or email for the duration of the work assignment, in addition to the standard reporting requirements of the contract.
Travel: Any non-local travel directly chargeable to this work assignment shall be submitted and approved by the Project Officer prior to the travel (see contract clause Local LC-31-08, Approval of Contractor Travel). It is expected that the Contractor will be requested to participate in a 2-day workshop in the Research Triangle (NC) area on dates to be determined.

EPA GREEN MEETING REQUIREMENTS: When soliciting quotes or offers for meeting and conference services on behalf of the EPA, the Contractor shall follow the contract EPAAR clause 1552.223-71, EPA Green Meetings and conferences. More information about EPA's Green Meetings initiative may be found on the internet at http://www.epa.gov/oppt/greenmeetings/.

VII. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM)
Monica Linnenbrink
919-541-1522
Linnenbrink.Monica@epa.gov

Alternate WAM
Michael Loughran
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EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-02

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	ToxCast Workshops
	Base Option Period Number 1	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	E. Rish Assessment Support

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$5,301.00	37
Total:	$5,301.00	37

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 11/21/2014	$5,301.00	37
Cumulative Approved:	$5,301.00	37

Work Assignment Manager Name: Monica Linnenbrink (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-1522 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-05

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Scientific Panel Internal Revi
	Base Option Period Number 1	

Contractor: ICF Incorporated, L.L.C.

Specify Section and paragraph of Contract SOW: Section A.1.(c) Human Health Assessment Documents

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2015 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Teresa Shannon (Signature) (Date)	Branch/Mail Code: Phone Number: 513-569-7596 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-05

TITLE: Technical Support for Scientific Panel Internal Review Meetings

Section and Paragraph of Contract SOW: Section A.1.(c) Human Health Assessment Documents

PERIOD OF PERFORMANCE: November 1, 2014 thru October 31, 2015

I. PURPOSE

This work assignment is a follow-on to work performed in the Base Period under Work Assignment # 0-05. The purpose of this Work Assignment (WA) is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) Office of Research and Development (ORD), National Center for Environmental Assessment-Cincinnati (NCEA-C), in obtaining technical support services for the scientific panel internal review meetings. The Contractor shall provide professional note-taking services to support this effort.

II. BACKGROUND

NCEA supports the Superfund Program by developing provisional toxicity values (PTVs) such as reference doses, reference concentrations, and cancer values for chemicals where such information is not available in EPA's Integrated Risk Information System (IRIS). Provisional toxicity values are documented in Provisional Toxicity Value documents.

In order to streamline the PTV review process and ensure consistency, an internal scientific review panel was established by NCEA-C to review each chemical and resolve technical issues prior to the completion of an external peer review and the clearance process. The scientific internal review panel meets on a regular basis (once per month or as deemed necessary) for approximately 3 hours per meeting. The Panel consists of seven technical reviewers (EPA senior scientists) and one professional note-taker.

III. STATEMENT OF WORK

Task 1: Establish Communication - Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the EPA WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan and Staffing Plan - The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, showing assigned personnel by task and the qualifications of the proposed personnel.

Qualifications - The Contractor shall provide a qualified professional note-taker with a minimum of 8 years of experience in risk assessment, toxicological terminology, and related topics.

Specific Requirements - The Contractor is requested to begin work under this WA immediately upon

receipt from the Contracting Officer, while simultaneously preparing a Work Plan.

Task 3: Preparation for Panel Meeting - The Contractor shall provide professional note-taker services to perform Tasks 3 – 6, for up to 10 Panel Meetings to be held during the period of performance of this WA. The professional note-taker services shall include preparing for each scientific review panel meeting by completing an overview of the designated PTV draft manuscripts and checklists to be reviewed during each meeting. During each Panel Meeting, a total of 1-3 chemicals will be discussed. Written information for each chemical typically ranges from 30-75 pages in length. Access to information for each chemical will be provided to the Contractor a minimum of five (5) business days in advance of each scheduled meeting by the EPA WAM. The Contractor shall obtain the required information through the Environmental Science Connector and/or the Health and Environmental Research Online (HERO) database.

Task 4: Schedule for Panel Meetings - The Contractor shall provide note-taker services via teleconference. All meetings will take place at the U.S. Environmental Protection Agency, Andrew W. Breidenbach Environmental Research Center, 26 W. Martin Luther King Drive, Cincinnati, OH, 45268. The meetings typically are held in the afternoon between noon and 5:00 pm. The meeting dates and times will be set by the EPA WAM at least 1 week in advance. The first Panel Meeting for this Performance Period will be determined by the EPA WAM. The Contractor will be notified by the EPA WAM of all scheduled meetings via written technical direction.

Task 5: Draft Written Reports - The Contractor shall provide a draft written report of the results of each scientific review panel meeting to the EPA WAM within 4 business days following the meeting. In response to the draft written report, the EPA WAM will provide any comments, changes, or questions to the Contractor within 5 business days after receipt.

Task 6: Final Written Reports - Upon receipt of the EPA's response, the Contractor shall provide a final written report of the results of each scientific review panel meeting to the EPA WAM within 5 business days.

IV. ANTICIPATED DELIVERABLES

All written deliverables shall be provided in electronic format in Microsoft Word.

V. DELIVERABLES AND SCHEDULE

Task 1 – Establish Communication	Within 3 days of start of WA
Task 2 – Work Plan and Staffing Plan	Begin work immediately and simultaneously prepare Work Plan and Staffing Plan within 15 calendar days after receipt of WA
Task 3 – Preparation	Prepare for scientific review panel meetings within 5 days of each meeting
Task 4 – Panel Meetings	Furnish professional note-taker to attend up to 10 Panel Meetings, as scheduled by the EPA WAM

Task 5 – Draft Written Report	After each Panel Meeting, provide a draft written report to the EPA WAM within 4 business days
Task 6 – Final Written Report	Upon receipt of WAM's response to each draft written report, provide a final written report to the EPA WAM within 5 business days

All deliverables shall be submitted electronically as Microsoft Word documents. Electronic (pdf) copies of all deliverables shall be sent to the EPA Project Officer (PO) shown below.

VI. MANAGEMENT CONTROLS

1. The Contractor shall certify there is no conflict of interest. The Contractor shall provide the following conflict of interest certification in the Work Plan:

> I certify that, to the best of my knowledge and belief, no actual, apparent, or potential organizational or individual conflicts of interest related to this WA exist. Personnel who perform work under this WA, or relating to the WA, have been informed of their obligation to report personal and organizational interests. All actual, apparent or potential organizational or individual conflicts of interest related to this WA have been reported to the EPA WAM or are attached, if applicable.

2. The Contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

3. All deliverables shall be reviewed for conformance to the requirements of this WA before being approved as final.

4. The Contractor shall comply with other applicable requirements for final WA reports stipulated in the Agreement.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(a) Formulation of Agency policy
(b) Selection of Agency priorities
(c) Development of Agency regulations

Should the Contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or Work Assignment, the contractor shall immediately contact the EPA WAM.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The Contractor shall hold a conference call with the EPA WAM at the initiation of the WA, and shall provide a bi-weekly update to the EPA WAM by telephone as necessary, or in the form of a report submitted via email, for the duration of the WA. The Contractor shall be prepared to participate in additional conference calls or email exchanges, as necessary.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM)

Teresa Shannon
513-569-7596
513-487-2542 (fax)
shannon.teresa@epa.gov

Alternate Work Assignment Manager (Alt. WAM)

Jay Zhao
513-569-7373
513-487-2542 (fax)
Email: zhao.jay@epa.gov

Mailing Address:
U.S. Environmental Protection Agency
National Center for Environmental Assessment
26 W. Martin Luther King Drive
MS-A110
Cincinnati, OH 45268

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-05

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015 Base Option Period Number 1	PTV Meeting Support

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	E. Risk Assessment Support

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$30,262.00	246
Total:	$30,262.00	246

Work Plan / Cost Estimate Approvals

Contractor WP Dated: 11/21/2014	Cost/Fee: $30,262.00	LOE: 246
Cumulative Approved:	Cost/Fee: $30,262.00	LOE: 246

Work Assignment Manager Name: Teresa Shannon (Signature) (Date)	Branch/Mail Code: Phone Number: 513-569-7596 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) 12/3/15 (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-07

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	SWG support for IRIS
	Base Option Period Number 1	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	A.1 and B.1,2,5

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/06/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	11/01/2013 To 10/31/2015		
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	Cost/Fee:	LOE:
Cumulative Approved:	Cost/Fee:	LOE:

Work Assignment Manager Name: John Fox (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8598 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-07

TITLE: Dose-response and Quantitative Analysis (SWG support for IRIS)

Principal Section & Paragraph of SOW: A.1 and B.1,2,5

PERIOD OF PERFORMANCE: November 6, 2014 – October 31, 2015

I. PURPOSE

This work assignment is a follow-on to work performed in the Base Period under Work Assignment # 0-07. The purpose of work assignment is to provide continued services to the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the completion of Dose-Response and Quantitative Analyses in Support of IRIS. More specifically, this work assignment will continue to provide dose-response analyses, statistical analyses, and other quantitative analyses and research as identified in the contract performance work statement, Sections A(1) and B(1,2, and 5). Data entry and data QA, and data management will be a part of these tasks. Reporting of results in tables of standard IRIS formats will be a part of these tasks.

II. BACKGROUND

EPA's Integrated Risk Information System (IRIS) is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to environmental contaminants. When supported by available data, the database provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic non-cancer health effects, and oral slope factors and inhalation unit risks for carcinogenic effects. Government and private entities use IRIS to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health. IRIS contains chemical-specific summaries of qualitative and quantitative health information in support of two steps of the risk assessment process, i.e., hazard identification and dose-response evaluation. IRIS information includes the reference dose for non-cancer health effects resulting from oral exposure (the RfD), the reference concentration for non-cancer health effects resulting from inhalation exposure (the RfC), and the carcinogen assessment for both oral and inhalation exposures. Combined with specific situational exposure assessment information, the summary health hazard information in IRIS may be used as a source in evaluating potential public health risks from environmental contaminants.

Under a previous contract, software utilities (DRAGON and BMDS-WIZARD) were developed for IRIS. These tools are based on Microsoft Access, MS/Excel, some VBA code, and BMDS software. The purpose of these tools is to expedite the entry and QA of information and data from toxicological studies, to expedite the production of tables for IRIS chemical assessments, and to expedite the conduct of dose-response analysis and related calculations and the review and reporting of results. These tools have greatly increased throughout and decreased effort for assembling and reporting information for IRIS assessments.

III. SCOPE OF WORK: TASKS AND DELIVERABLES

Requirements Specific to this PWS

This PWS supports continued development and modification of software tools (DRAGON, WIZARD, and the dosimetry tool, and exposure-response array) that are based on Microsoft Access, Microsoft Excel, and associated Visual Basic for Applications code.

The contractor shall provide personnel who are proficient with the software tools DRAGON, WIZARD, Microsoft Access, Microsoft Excel, and knowledgeable regarding dosimetric conversions BMDS (Benchmark Dose Software; at http://www.epa.gov/ncea/bmds) is the primary software tool used by IRIS for dose-response modeling, and it is used by DRAGON and WIZARD to conduct dose-response modeling. Therefore, the contractor shall provide personnel who are already experienced with benchmark dose modeling, the use of BMDS, and the formats of BMDS auxiliary files (*.(d),*.dax, *.ssn, *.opt).

Under this PWS, an episode of work (aka "request") will be initiated by written Technical Direction (TD). Each request will specify deadlines for delivering drafts and final work products. An initiating TD will identify the data and the specific Tasks (enumerated below) to be performed.

The Contractor shall prepare documents in the format specified in the current IRIS standard operating procedures and templates (to be provided by EPA). Recent examples of final and draft assessments for other chemicals may also serve as models. Documents shall be technically edited for format and grammar before being delivered to the EPA Work Assignment Manager.

Agency guidance will be applied and exceptions to such guidance will be clearly noted. Agency guidance should be used: (a) to determine the suitability of studies and data used; (b) to guide the preparation of data and the adjustment of doses or concentrations for intermittent and time-varying exposures and less-than-lifetime exposures; (c) to guide the conduct of dose-response modeling and model selection; (d) to guide the development of RfC/RfD values, cancer slope factors, and all other subject matter included in Chapters 5 and 6 of a Toxicological Review.

The work shall be conducted so as to be consistent with EPA's *Benchmark Dose Technical Guidance Document* and other relevant EPA guidelines (e.g., guidelines for carcinogen risk assessment, neurotoxicity, reproductive toxicity, developmental toxicity, and inhalation dosimetry (see documents at http://www.epa.gov/iris/backgrd.html). Quantitative dose-response analyses shall be conducted and reported according to the *Annotated Checklist of Best Practices for Dose-Response Analyses for IRIS*, to be provided by EPA. If any exceptions to the foregoing guidance and checklist are required for an analysis, they should be noted and explained.

Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.(d), *.out, *opt, *.ssn]). The contractor shall use the most recent issue of BMDS (BMDS 2.x) for dose-response analyses, where this is feasible and efficient; otherwise, the contractor shall use the latest versions of BMDS executable 'modules' (e.g., multistage.exe) if the latest GUI is not used [these modules are installed with BMDS 2.x].

Input data and BMDS accessory files developed under this Task for the various dose-response analyses shall be delivered. This includes spreadsheets, input files to the BMDS Wizard, and accessory files used and produced by BMDS (e.g., BMDS related files: *.(d), *.set, *.dax, *.opt, *.ssn, *.out, *.002, *.plt, *.emf, and Excel export files from BMDS2). These materials will be organized in subdirectories or by file names so as to distinguish cancer and noncancer effects, exposure routes (inhalation, diet, drinking water), and continuous vs.

dichotomous (quantal) responses. These files shall be named or described (e.g. in a Read_Me.txt file or other document) or otherwise organized sufficiently that the data sets and endpoints are recognizable. These materials will be transmitted in electronic form, e.g., by email in a ZIP file or delivered physically on a CDROM.

The contactor will develop and maintain internal documentation and data pertaining to all assumptions, data sources, databases, procedures, statistical analyses, and computer programming code, scripts, and software instructions used to support and execute EPA's requirements and deliverables, in order that results can be replicated. The contactor will provide access to this internal documentation upon request by the EPA WAM (Work Assignment Manager) or EPA Project Officer.

Task 1: Quality Assurance Project Plan (QAPP)

The contractor shall prepare Quality Assurance Project Plan (QAPP), stating that the QAPP will be observed during the conduct of this work assignment.

The contractor shall develop a quality assurance project plan (QAPP) for this project. The QAPP shall be submitted simultaneously with the work plan for approval. The contractor shall not perform any work under the other tasks of this Project until the contractor receives a signature page from EPA for the QAPP, showing approvals by the Work Assignment Manager, the contract Project Officer, and NCEA's QA official.

Deliverables: QAPP
Due Date: 15 days after issuance of this Performance Work Statement (PWS).

Task 2. Data Entry and Data QA

Following CO approval of the workplan and QAPP, the contractor shall review the data sources to identify data for each endpoint, enter the data into an electronic medium (if not already provided in this form), and verify the data. All data shall be verified as correctly entered from the source. Source publications will usually be accessed using EPA's HERO database.

The contactor is not responsible for verifying secondary data quality for studies and endpoints identified by the EPA WAM unless required to do so in the written Technical Direction pertaining to a specific request.

The contactor will provide, to the EPA WAM, spreadsheets that indicate the source of the individual data element from a study by reference to the page, table, figure, footnote, etc., from the original report being cited. Data will be entered in the units provided in the original paper, with any necessary transformations explicitly performed in the spreadsheet. Units conversions and adjustments for intermittent or non-constant exposure shall be documented explicitly for each data set, with comments as needed. Possible cases of systematic differences in survival between dose groups (typically, lower survival in high dose groups) will be 'flagged'.

When a request involves multiple studies, data will be assembled and organized in either the BMDS WIZARD or in DRAGON, unless the contractor and the EPA WAM agree not to do so.

Deliverables: Notification of completion to EPA WAM by email or telephone. As necessary, questions and problems regarding data will be delivered, with proposed methods of resolution.
Data will be delivered after task 2 completion only if specifically requested (usually the data will be delivered with results of benchmark dose analyses under the Tasks that follow this one).

Due Dates: To be specified either in written technical direction after consultation with the contractor, or, if not so specified, then the greater of: (a) 2 working days or (b) one working day for every 12 distinct endpoints, or (c) one working day for every 8 distinct studies.

Task 3: Non-Cancer Data Analysis and Benchmark Dose Modeling

Under this task, the contractor will evaluate non-cancer data sets for dose-response modeling in a manner consistent with EPA's Benchmark Dose Technical Guidance Document and Annotated Checklist of Best Practices for Dose-Response Analyses for IRIS. The contractor will consult with the EPA WAM as to potential problems with particular experiments and data sets. Prior to modeling data, the contractor will perform any necessary dosimetric adjustments and/or conversions, select appropriate benchmark responses (BMRs) for each endpoint, identify important or unusual statistical issues, and flag data not amenable to benchmark dose modeling. Additionally, the contractor will perform data verification and documentation as outlined in Task 2 prior to dose-response modeling.

To facilitate comparison of multiple candidate PODs, summary results for BMDs, BMDLs, NOAELs and LOAELs will be reported in terms of Human-Equivalent Dose or Concentration (HED/HEC). For chronic and subchronic oral (ingestion) exposures (specifically excluding developmental and short-term studies), a $BW^{3/4}$ default animal-human conversion be made. Reporting units will be mg/kg-day for oral exposure and either ppm or mg/m^3 for inhalation exposure. RfDs will be reported in mg/kg-day and RfCs will be reported in mg/m^3.

The contractor will model data amenable to benchmark dose modeling using EPA's BMDS2.x. Results will be summarized in tables that report key statistics for model goodness of fit (AIC, p-value for goodness of fit, degrees of freedom for the Chi-square test, and largest scaled Chi-square residual). Based on these results along with considerations of biological relevance, the contractor will identify candidate data sets, endpoints, and models that could be used as a basis for a POD for both ingestion and inhalation exposure routes, as the data permit. If so directed in writing, the contractor will summarize results in tables in an MS/Word document(s); tables and footnotes will be modeled after current IRIS table templates.

Deliverable: spreadsheets holding input data; output (analysis) results by data set with recommended models; summary tables showing key results for selected models for the various datasets (endpoints) by exposure route

Due Date: 7 calendar days after: completion of data entry and QA, and resolution of any questions or issues referred to the EPA WAM regarding the data
Revisions – dates to be specified in written technical direction

Task 4: Cancer data analysis and dose-response modeling

Under this task, the contractor will review the study reports identified by the EPA WAM to identify data sets on cancer incidence amenable to analysis of individual tumor sites. For both ingestion and inhalation exposure routes, as the data permit, cancer data amenable to benchmark dose modeling will be prepared and verified as outlined in Task 2.

The contractor will also identify studies amenable to modeling risk from multiple tumors per animal (when data exists for multiple tumor sites in one study for one sex of one rodent strain, EPA may request an analysis of risk from multiple tumors using the MS_COMBO program or using the "multi-tumor" option of BMDS).

Individual tumor data will be fitted using the 'multistage cancer model' of BMDS (with coefficients constrained to be non-negative). Multistage model order selection will be based upon a minimum AIC criterion unless otherwise specified in writing.

After conducting BMDS modeling, the contractor will identify those data sets, endpoints, and models (i.e., orders of the multistage model) that could be used as a basis for unit risk/cancer slope factor. If so directed in writing, the contractor will summarize results in tables in an MS/Word document(s); tables and footnotes will be modeled after current IRIS table templates.

Deliverable: spreadsheets holding input data; output (analysis) results by data set with recommended models; summary tables showing key results for selected models for the various datasets (endpoints) by exposure route

Due Date: 7 calendar days after: completion of data entry and QA, and resolution of any questions or issues referred to the EPA WAM regarding the data
Revisions – dates to be specified in written technical direction

Task 5: Time to Tumor Analysis

The contractor may be requested to review cancer bioassay studies (provided by the EPA WAM) to identify and propose those for which time to tumor analysis may need to be applied, or such studies may be identified by the EPA WAM. Time-to-tumor analysis would need to be applied if survival differs substantially among the dose groups.

The contractor will use the "MSW" program for time-to-tumor analysis and will report any failures of the MSW program to solve the BMDL. If this occurs, the program "ToxRisk" (version 5.3) will be used to obtain a BMDL. Subsequently, parameter estimates and BMD resulting from MSW and ToxRisk will be compared to determine similarity. The contractor will also call attention to any instances of parameter estimates on a boundary. Where higher-order coefficients are nonzero, estimates will be presented for all model orders between 1 and the number of dose groups less 1. The EPA WAM may request a conventional BMDS cancer-model analysis based on poly-3 weights applied to the individual animal data, as an alternative to time-to-tumor modeling.

Deliverables: input and output files used/produced by software to fulfill this task (text files and/or spreadsheets); a report with tables summarizing the data, data sources, and results, suitable for inclusion in an Appendix to a Toxicological Review

Due Date: to be specified in written technical direction. EPA will not require completion of more than 6 data sets per work day (to include data entry and QA, data analysis, and reporting) except by prior agreement with the contractor

Task 6: Prepare Draft Materials for IRIS Toxicological Reviews

The contractor, when requested in a technical directive, shall prepare draft portions of an IRIS Toxicological Review, relevant to dose-response or quantitative analyses conducted under other tasks herein, and following the style of the IRIS template for Toxicological Reviews (to be provided by EPA). Drafts may include Evidence Tables, Study Summaries, exposure-response arrays, dose-response modeling, selection of an

oral reference dose (RfD), inhalation reference concentration (RfC), cancer modeling (including derivation of a cancer slope factor and inhalation unit risk), Chapter 2 text and tables, Appendix materials, and related narratives.

Deliverables and Due Dates:

Drafts with supporting materials, date to specified in written technical direction.
Input data sets and results (output), and supporting results & documentation, three weeks after completion of dose-response analyses.
Due dates for revisions may be specified in written technical direction; if not so specified, then within 10 working days of receipt of comments and written technical direction from EPA

Task 7. Study and Endpoint Screening and Selection for Hazard ID and Dose-Response Analysis

This task may require:

- review of studies for adequacy to support inferences about toxicity and carcinogenicity, using decision criteria either provided by EPA or proposed by the contractor and confirmed by EPA

- review of studies to support dose-response analysis, using decision criteria either provided by EPA or proposed by the contractor and confirmed by EPA

- preparation of "evidence tables" in the current IRIS format

- other tabulations of studies using a layout provided by EPA or proposed by the contractor and confirmed by EPA, and computations needed to calculate results for such tabulations

- graphical presentations comparing studies and endpoints quantitatively and qualitatively, including but not limited to exposure-response arrays and forest plots, and computations needed to calculate results for such plots

If so requested, the contractor will document in such tables the preliminary decisions (including rationales) about critical endpoints, to include (of so directed) MOA, sensitive populations, and candidate/principal studies for hazard evaluation and RfV derivation.

If so requested, the contractor will document the details that support preliminary decisions regarding regarding potential critical endpoints, MOA, sensitive populations, and candidate/principal studies.

The EPA WAM will communicate detailed requirements by Technical Directions when this Task is undertaken, and will provide examples from recent Assessment documents.

Deliverables: Spreadsheet worksheets and Word tables; supporting narrative and appendices when requested
Due Dates:

Drafts with supporting materials, date to specified in written technical direction.
Input data sets and results (output), and supporting results & documentation, three weeks after completion of dose-response analyses.
Due dates for revisions may be specified in written technical direction; if not so specified, then within 10 working days of receipt of comments and written technical direction from EPA

V. SCHEDULE OF DELIVERABLES

This schedule and the deliverables dates specified under each Task above may be changed using written Technical Direction.

Task	**Schedule** (*all days are elapsed calendar days unless otherwise stated)
1. Quality Assurance Project Plan	15 days* after receipt of this PWS
2. Data Entry and QA	To be specified in written technical direction. If not so specified, then the greater of: (a) 2 working days or (b) one working day for every 12 distinct endpoints, or (c) one working day for every 8 distinct studies.
3. Non-Cancer Modeling	To be specified in written technical direction. If not so specified, then 7 calendar days after: completion of data entry and QA, and resolution of any questions or issues referred to the EPA WAM regarding the data
4. Cancer Modeling	To be specified in written technical direction. If not so specified, then 7 calendar days after: completion of data entry and QA, and resolution of any questions or issues referred to the EPA WAM regarding the data
5. Time-to-Tumor Modeling	To be specified in written technical direction. EPA will not require completion of more than 6 data sets per work day (to include data entry and QA, data analysis, and reporting) except by prior agreement with the contractor
6. Draft Materials for IRIS Tox. Reviews	Drafts with supporting materials, date to specified in written technical direction. Input data sets and results (output), and supporting results & documentation, three weeks after completion of dose-response analyses. Due dates for revisions may be specified in written technical direction; if not so specified, then within 10 working days of receipt of comments and written technical direction from EPA
7. Study and Endpoint Screening	Drafts with supporting materials, date to specified in written technical direction. Input data sets and results (output), and supporting results & documentation, three weeks after completion of dose-response analyses. Due dates for revisions may be specified in written technical direction; if not so specified, then within 10 working days of receipt of comments and written technical direction from EPA

VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA. The Contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

VII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall provide regular updates on progress and any issues that need to be resolved to the WAM by telephone or by email. Any technical directions made during informal discussions shall be issued promptly by the EPA WAM in writing (to include email).

VIII. EPA CONTACTS

EPA Work Assignment Manager (WAM)

John Fox
703-347- 8598 (voice), 703-347-8690 (fax), email Fox.John@epa.gov

Mailing Address:
U.S. EPA, ORD/NCEA-Washington (Mail Code 8601 P)
1200 Pennsylvania Ave, NW, Washington, D.C. 20460

Courier Deliveries:
U.S.E.P.A. Office of Research and Development, National Center for Environmental Assessment
Two Potomac Yard North, 7th Floor N-7954, 2733 S. Crystal Drive, Arlington, VA 22202

EPA Alternate Work Assignment Manager (Alt-WAM)
Christine Cai, 703-347- 8517 (voice), 703-347-8689 (fax), email cai.christine@epa.gov

(same as for WAM)

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-07

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Dose-resp sppt for IRIS
	Base Option Period Number 1	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	A.1 and B

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/06/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$33,691.00	348
Total:	$33,691.00	348

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 11/21/2014	$33,691.00	348
Cumulative Approved:	$33,691.00	348

Work Assignment Manager Name: John Fox (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8598 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-08

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Software Tools
	Base Option Period Number 1	

Contractor: ICF Incorporated, L.L.C.

Specify Section and paragraph of Contract SOW: E. Risk Assessment Data & Computer Tools

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	11/01/2013 To 10/31/2015		
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	Cost/Fee:	LOE:
Cumulative Approved:	Cost/Fee:	LOE:

Work Assignment Manager Name: John Fox (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8598 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-08

TITLE: Software Tools to Support IRIS Data Management, Analysis and Reporting

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Principal Section & Paragraph of SOW: C. Risk Assessment Data Bases and Computer Tools

PERIOD OF PERFORMANCE: November 1, 2014 - October 31, 2015

I. PURPOSE

This work assignment is a follow-on to work performed in the Base Period under Work Assignment # 0-08. The purpose of this Performance Work Statement (PWS) is to provide continued services to the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the completion of "Software Tools to Support IRIS Data Management, Analysis and Reporting." More specifically, this work assignment will continue to provide software tools and templates to support data management and quality assurance, summarization and analysis of data (e.g., for hazard evaluation and dose-response modeling) and the organization and reporting of these data and analyses, primarily for the preparation of toxicological reviews by NCEA's IRIS program.

II. BACKGROUND

EPA's Integrated Risk Information System (IRIS) is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to environmental contaminants. When supported by available data, the database provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic non-cancer health effects, and oral slope factors and inhalation unit risks for carcinogenic effects. Government and private entities use IRIS to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health. IRIS contains chemical-specific summaries of qualitative and quantitative health information in support of two steps of the risk assessment process, i.e., hazard identification and dose-response evaluation. IRIS information includes the reference dose for non-cancer health effects resulting from oral exposure (the RfD), the reference concentration for non-cancer health effects resulting from inhalation exposure (the RfC), and the carcinogen assessment for both oral and inhalation exposures. Combined with specific situational exposure assessment information, the summary health hazard information in IRIS may be used as a source in evaluating potential public health risks from environmental contaminants.

Under a previous contract, software utilities (DRAGON and BMDS-WIZARD) were developed for IRIS. These tools are based on Microsoft Access, MS/Excel, some VBA code, and BMDS software. The purpose of these tools is to expedite the entry and QA of information and data from toxicological studies, to expedite the production of tables for IRIS chemical assessments, and to expedite the conduct of dose-response analysis and related calculations and the review and reporting of results. These tools have greatly increased throughout and decreased effort for assembling and reporting information for IRIS assessments.

III. SCOPE OF WORK: TASKS AND DELIVERABLES

Requirements Specific to this PWS

This PWS supports continued development and modification of software tools (DRAGON, WIZARD, and the dosimetry tool, and exposure-response array) that are based on Microsoft Access, Microsoft Excel, and associated Visual Basic for Applications code. Therefore, the contractor shall provide personnel who are already expert in the areas of (a) QA and revision control for program codes, (b) Visual Basic for Applications programming, (c) applications based on commercial spreadsheets (specifically, Microsoft Excel) and (d) commercial database management systems (specifically, Microsoft Access).

BMDS (Benchmark Dose Software; at http://www.epa.gov/ncea/bmds) is the primary software tool used by IRIS for dose-response modeling, and it is used by DRAGON and WIZARD to conduct dose-response modeling. Therefore, the contractor shall provide personnel who are already experienced with benchmark dose modeling, the use of BMDS, and the formats of BMDS auxiliary files (*.(d),*.dax, *.ssn, *.opt).

Task 1: Quality Assurance Project Plan (QAPP)

The contractor shall prepare Quality Assurance Project Plan (QAPP), stating that the QAPP will be observed during the conduct of this work assignment.

The contractor shall develop a quality assurance project plan (QAPP) for this project. The QAPP shall be submitted simultaneously with the work plan for approval. The contractor shall not perform any work under the other tasks of this Project until the contractor receives a signature page from EPA for the QAPP, showing approvals by the Work Assignment Manager, the contract Project Officer, and NCEA's QA official.

Deliverables: QAPP
Due Date: 20 days after issuance of this Performance Work Statement (PWS).

Task 2. MS/Word templates

Background: "Streamlining" (revising the content and format) of IRIS toxicological reviews is an ongoing process which will be informed by feedback from the National Academy of Sciences, reviewers, and stakeholders. From time to time, EPA may require new or revised MS-Word templates (associated with BMDS Wizard and Dragon) as IRIS revises its formatting of toxicological reviews. EPA may also require changes or additions to the data-management, calculation and reporting capabilities of Wizard and Dragon to support changes in data calculations and changes in reporting for toxicological reviews.

The contractor will create or revise (as appropriate) MS/Word templates and styles used to create tables for use in IRIS toxicological reviews. These include (but are not limited to) Study Summary tables, tables summarizing modeling results, and Evidence Tables.

EPA expects modifications to MS/Word templates associated with epiDRAGON, reflecting the anticipated modifications and additions to the software as described in Task 3. The contractor will create or revise (as appropriate) MS/Word templates and styles used to create tables for use in IRIS toxicological reviews. These include (but are not limited to) Study Summary tables, tables summarizing modeling results, and Evidence Tables.

EPA expects to request one revision to each template currently in use, and development of two new templates.

Deliverables: revised MS-Word templates
Due Dates: to be specified in written technical direction

Task 3. DRAGON (Dose Response Analytical Generator and Organizational Network)

EPA expects to request additions of new data fields and simple calculations in Dragon, to support reporting needs for evidence tables. For the purpose of costing this PWS, the contractor should assume that a dozen such changes may be requested by EPA. Changes or additions to data fields for developmental studies can be expected. Data forms or fields for neuro-developmental or neuro-toxicological studies will be added.

Examples of such data fields and calculations added in the past included: indicators for significance-test results from original publication, comparing treatments to control (P-values and NA when not available); calculation of 'percent change' from control for continuous responses; calculation of empirical extra-risk for treated groups for dichotomous data.

This Task covers additions to and modifications of various "modules"in DRAGON and their integration into a single databases system. Modules include but are not limited to "epiDRAGON", "cellDRAGON", "animalDRAGON", and "Management module".

Export and import capabilities (e.g. for data exchange with Meta-data Viewer, Graphpad, and Excel) may be requested. Forms, or export capabilities, or reporting formats compatible with HERO may be requested.

The contractor will verify correct operation of DRAGON during development and after completion of a beta version, and will report periodically to the WAM on results of testing and on measures to correct any problems found by testing or in use.

This work assignment will continue and extend development of DRAGON but shall not duplicate work already done for the federal government. [For example, modifications to DRAGON made under another work assignment would not be repeated under this work assignment.]

EPA expects to continue to request additions of data fields and capabilities in "epiDRAGON," to support reporting needs for study methods tables, evidence tables, exposure-response arrays, and dose-response analysis. This may include specialized fields for different study designs, exposure scenarios, and outcome types (e.g., cancer, neurodevelopmental, etc.). Modifications to epiDRAGON are expected to be iterative, with periodic evaluation performed using 'test' or 'practice' sets of data/studies. The contractor will verify correct operation of epiDRAGON during development and after completion of a beta version, and will report periodically to the WAM on results of testing and on measures to correct any problems found by testing or in use. This work assignment will continue and extend development of epiDRAGON but shall not duplicate work already done for the federal government. [For example, modifications to epiDRAGON made under another work assignment would not be repeated under this work assignment.]

<u>Deliverables and due dates</u>:
New and revised fields and forms will be specified in written technical direction
Drafts of DRAGON for review - arranged by consultation with WAM
Reports on testing with 'practice data' – approx. every 4 weeks during development
Wizard modeling templates – to be requested in written technical directions
Word report/table templates – to be requested in written technical directions

Task 4. User Manuals and Tutorials

User manuals will be developed for DRAGON and WIZARD (these will also cover use of the imbedded dosimetry tool). Scope: the manuals will provide users with instructions for use, but are not expected to explain the workings of Access or Excel or the details of the associated VBA code. Manuals will be provided with databases that may be used in the manuals as examples and can be used by users as templates. Necessary information will be provided separately on any modifications (including VBA code) and configuration steps needed to use these databases on a proxy server. Manuals will be revised within one month of any significant changes to DRAGON or WIZARD.

Tutorials will be provided (dates to be determined in consultation with EPA). These may take the form of demonstration/lectures, either on-site at EPA locations or as webinars. Provision will be made for user questions and answers. For the purpose of costing this PWS, the contractor should assume that EPA would request eight demonstration/lectures, four at each of two EPA locations. Some might be conducted via webinar, but others might be in-person at different EPA locations. These tutorials may cover different modules separately (e.g., Animal module, Epidemiology module) and may emphasize different forms (e.g., developmental data) for different IRIS workgroups.

Deliverables and due dates:

Manuals: draft within 15 working days of approval of this task; revised drafts within 10 working days after EPA returns comments

Tutorials: dates to be arranged in consultation with EPA

Task 5. User Group Meetings

Meetings will be arranged as telephone conferences and/or web conferences. The contractor shall coordinate and organize meetings, distribute agendas, and report minutes and action items.

Meeting frequency will be determined by consultation with EPA; expected frequency is monthly to bi-monthly, but ad-hoc meetings may be called (as needed) to discuss new modules and new or changed features. Meetings may be arranged separately for different user groups, for example, users of epi-DRAGON and users of Animal-DRAGON. Details of attendees and subject matter will be arranged in consultation with EPA. The principal purposes are (a) to gather input from users regarding DRAGON features and usability (existing or planned) and (b) to share information about and reconcile needs of different users both within EPA (including HERO users and staff) and in other federal agencies.

Deadlines: meeting dates and times to be determined in consultation with EPA and other users

Task 6. BMDS WIZARD

The BMDS WIZARD will be updated to accommodate changes to BMDS as these occur and if BMDS changes require modifications to the WIZARD. The contractor should notify the WAM when a need is determined; work will then be initiated after receipt of written technical direction from EPA

Deliverables: revised BMDS WIZARD
Deadlines: to be specified in written technical direction

V. SCHEDULE OF DELIVERABLES

This schedule and the deliverables dates specified under each Task above may be changed using written Technical Direction.

Task	**Schedule** (*all days are elapsed calendar days unless otherwise stated)
1. Quality Assurance Project Plan	15 days* after receipt of this PWS
2. MS/Word templates	to be specified in written technical direction
3. DRAGON	Drafts of DRAGON for review: arranged by consultation with WAM Developmental forms: mid-December 2013
	Oral reports on testing with practice data or in use for EPA projects – approx. every 4 weeks during development
	Beta versions of DRAGON after adding new modules - arranged by consultation with WAM
	Revisions in response to EPA comments - 14 work days after receiving technical direction
4. User Manuals and Tutorials	Manuals: draft within 20 working days of approval of this task. Revised drafts within 10 working days after EPA returns comments. Tutorials: dates to be arranged in consultation with EPA
5. User Group Meetings	to be determined in consultation with EPA and other users
6. BMDS WIZARD	to be specified in written technical direction

VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA. The Contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

VII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall provide regular updates on progress and any issues that need to be resolved to the WAM by telephone or by email. Any technical directions made during informal discussions shall be issued promptly by the EPA WAM in writing (to include email).

VIII. EPA CONTACTS

EPA Project Officer (PO)

Melissa Revely-Wilson, Acquisition Specialist
Office of Research and Development (8601-P)
Office of Administrative and Research Support
Extramural Management Division - Contracts Branch
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1200 Pennsylvania Avenue, NW
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EPA Work Assignment Manager (WAM)

John Fox
703-347- 8598 (voice), 703-347-8690 (fax), email Fox.John@epa.gov

Mailing Address:
U.S. EPA, ORD/NCEA-Washington (Mail Code 8601 P)
1200 Pennsylvania Ave, NW, Washington, D.C. 20460

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U.S.E.P.A. Office of Research and Development, National Center for Environmental Assessment
Two Potomac Yard North, 7th Floor N-7954, 2733 S. Crystal Drive, Arlington, VA 22202

EPA Alternate Work Assignment Manager (Alt-WAM)

Glinda Cooper, 703-347-8636 (voice), email Cooper.Glinda@epa.gov

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-08

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	IRIS software tools
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: C. Risk Assessment Data Bases and Computer Tools

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$41,684.00	484
Total:	$41,684.00	484

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 11/21/2015	$41,684.00	484
Cumulative Approved:	$41,684.00	484

Work Assignment Manager Name: John Fox (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8598 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-09

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Change Impacts in Ecosystems
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 12/07/2014 To 10/31/2015

Comments:
B. Risk Assessment Methods Research and Development: 5. Conduct Statistical Analyses and Modeling. C. Risk Assessment Data Bases and Computer Tools: 1. Technical Support D. Analysis, Document, and Issue Paper Preparation

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Britta Bierwagen (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8613 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-09

TITLE: Summary of Monitoring and Long-Term Observing Network Capabilities to Detect Global Change Impacts in Ecosystems

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Specify Section & Paragraph SOW: Please select from the following:

B. Risk Assessment Methods Research and Development: 5. Conduct Statistical Analyses and Modeling.
C. Risk Assessment Data Bases and Computer Tools: 1. Technical Support
D. Analysis, Document, and Issue Paper Preparation

PERIOD OF PERFORMANCE: *CO award to 10/31/2015*

I. PURPOSE

This work assignment (WA) is a follow-on to work performed in the Base Period under WA # 0-09. The purpose of this WA is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the form of compiling and analyzing data on ecosystem monitoring and observing networks and to summarize the assessment of monitoring and observing network capabilities. This WA is consistent with the purpose and scope of Contract EP-C-14-001.

II. BACKGROUND

This WA builds on previous EPA work that developed a survey for federal managers of monitoring and observing networks related to terrestrial and aquatic ecosystems. This WA re-deploys the online survey, follows up with telephone conversations, collects responses, and analyzes the responses according to an analysis plan provided by EPA. The results of the survey and analyses will be used for a publication written in coordination with the U.S. Global Change Research Program's (USGCRP) Biodiversity and Ecosystems Cluster. The analyses of existing monitoring and observing systems will complement the USGCRP's efforts to develop a system of indicators of climate change as part of the National Climate Assessment.

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, Call Schedule, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule (including regular calls), budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work

Plan, that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the basic science areas required to complete this WA.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "*EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs* (QAPP)"; "*EPA Requirements for Quality Assurance Project Plans (QA/R-5)*"; and "Appendix A. *Guidance on Quality Assurance Project Plans for Secondary Research Data.*"

The QAPP shall be submitted simultaneously with the Work Plan for approval. The Contractor shall not perform any work on subsequent tasks under this WA until the Work Plan and QAPP are reviewed and approved.

Task 3. Update contact and network list, deploy survey, and collect results

The Contractor shall update the contact information for appropriate federal managers (organized by agency) of ecosystem observing networks and any new networks, post the existing survey online, and prepare an "opt-in" email for federal agency representatives to distribute to federal managers within 4 weeks of WA approval. Survey entries shall be collected in a suitable database for analysis. The survey shall remain open until Task 5 is initiated.

Task 4. Follow-up with federal managers

The Contractor shall contact federal managers of ecosystem observing networks who have not responded online to the survey and discuss draft answers of survey questions. The contractor shall fill in the draft answers using available information about the network. It is anticipated that the contractor may need to contact up to 50 federal managers. Contacting federal managers shall commence 2 weeks after agency representatives have sent survey invitations and have not received opt-in emails.

Task 5. Analyze and present results to federal partners

The Contractor shall analyze the respondents' entries, due 3 weeks after Task 4 is complete. The contractor then shall schedule a call with EPA WAM to discuss draft analysis results within 2 weeks of sending draft results. The Contractor then shall prepare presentation materials for a meeting of the USGCRP Biodiversity and Ecosystems Cluster and other federal partners that will be scheduled within a month of the EPA WAM's receipt of draft results. The goal of this Cluster meeting will be to review survey results and draft analyses. After receiving input from the Cluster meeting and comments from the WAM on draft results, the Contractor shall implement revisions and any additional analyses, due within 2 weeks. Final results are due 1 weeks after receiving comments from the WAM.

Task 6. Draft journal article and review responses

The contractor shall summarize results of the database analysis, particularly with respect to detecting impacts related to climate changes. This document shall be in a form suitable for publication in a journal such as Ecology Letters or BioScience. A draft of the document is due to the WAM 2 weeks after completing Task 5. The WAM will circulate the draft within the USGCRP group for comments. A final document is due 2 weeks after receiving comments from the WAM and USGCRP group members.

The Contractor shall assist the WAM in addressing comments generated during internal EPA and external journal reviews. Revised article and comment-response document are due 3 weeks after receiving comments from WAM.

Task 7. Website materials

The Contractor shall develop web pages for a web portal that allows users to access the database of networks and survey information collected. It is likely that this web portal and associated explanatory pages may be hosted by either the USGCRP or EPA. The WAM will provide the Contractor with contact information for the webmaster where the web portal will be housed. The Contractor shall follow the web guidelines of the hosting institution. The Contractor shall submit draft web pages to be reviewed by USGCRP Cluster members and webmaster of the hosting institution 2 weeks after completing Task 5. Final web pages are due 3 weeks after receiving comments from WAM.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.(d), *.out, *opt, *.ssn]).

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. QAPP Call schedule	20 days after award Regular calls throughout WA
Task 3. Updated contact list, online survey and opt-in email	4 weeks after WA approval
Task 4. Manager follow-up	2 weeks after emails sent
Task 5. Analyze and present results	Draft analysis due 3 weeks after completing Task 4 Revised results due 2 weeks after call Presentation materials due for USGCRP meeting Revised results 2 weeks after receiving input from USGCRP meeting and comments from WAM Final results due 1 week after receiving comments from WAM
Task 6. Draft article and responses	Draft article 2 weeks after completing Task 5 Internal review draft 2 weeks after receiving comments from WAM External review draft 3 weeks after receiving comments from WAM Final draft to journal 3 weeks after receiving comments from WAM
Task 7. Web materials	Draft web pages for web portal 2 weeks after completing Task 5 Final web pages 3 weeks after receiving comments from WAM

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Task Order Manager (WAM)	**Alternate Task Order Manager (AWAM)**
Name: Britta Bierwagen	Name: Susan Julius
Office: ORD/NCEA/GCRP 1200 Pennsylvania Ave., NW (MC 8601P) Washington, DC 20460	Office: ORD/NCEA/GCRP 1200 Pennsylvania Ave., NW (MC 8601P) Washington, DC 20460
Phone: 703-347-8613	Phone: 703-347-8619
Fax: 703-347-8694	Fax: 703-347-8694
Email: Bierwagen.Britta@epa.gov	Email: Julius.Susan@epa.gov

Appendix A

Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

FOCUS: the work not only addresses the area of inquiry under consideration but also contributes to its understanding;
VERIFY: the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;
INTEGRITY: Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?
RIGOR: the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;
UTILITY: the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.
CLARITY: Is it written clearly and appropriately for the nature of the study?

Use the check list on the following page to evaluate the key studies.

DATA CHECKLIST FOR EVALUATING A STUDY

1.) Bibliographic identification of the study.

Study Identifiers:
Author(s):
Title:
Study Citation:
Storage location (e.g., library, facility archive, personal archive):

2.) Why is the study key to the particular project? (For example, is the study an example of new research or confirmation of previous work? Is the study's population larger or followed for a longer period of time than before, is the methodology better than other studies or corrective of problems in previous studies, or do the results provide new insight into the problem?)

3.) Summarize the study structure and methodology. What sampling techniques and statistical tests are used?

4.) Potential problem areas in the study; consider: study design, factors occurring within and outside of the study which may affect its validity, sampling errors, and any other perceived weaknesses.

5.) Do any data used from sources outside of the study seem reliable and generally free of measurement error? Discuss and give examples.

6.) Evaluate the study in terms of the appropriateness of the analytical methodology. In responding, consider the following questions:

Are research questions clearly stated; dependent and independent variables clearly defined?

Do the authors explain the type of data obtained from measures of the variables?

Are statistical methods adequately described; are they justified?

Is a source provided for the any statistical software used to analyze the data?

Is the purpose of the analysis clear?

Are any scoring systems described?

Are potential confounders adequately controlled for in the analysis?

Are analytic specifications of the variables consistent with the evaluation questions or hypotheses under study?

Is the unit of analysis specified clearly?

If statistical tests are used to determine comparability or difference, are p values provided; is the practical significance of these findings, as contrasted with the statistical significance, discussed?

7.) Evaluate the study's results. Consider the following questions:

Are study questions (objectives, hypotheses) clear?

Are all study questions answered?

Are negative findings presented?

Are missing data explained?

Are text and tables, figures, and graphs consistent?

8.) Evaluate the study's conclusions. Consider the following questions:

Are the conclusions based on the study's data in that findings are applied only to the sample that was included in the research?

When the authors compare their findings with those from another study, do the authors demonstrate the similarity of the two studies?

Does the author discuss limitations of design, sampling, data collection, etc.?

To what extent do the limitations affect one's confidence in the conclusions?

9.) How strong is the study, overall; relative to other similar studies? Do its weaknesses jeopardize its being a key study, or is it usable despite the reservations?

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-09

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Change Impacts in Ecosystems
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 12/07/2014 To 10/31/2015

Comments:

[ ] Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): [ ]

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$79,898.00	802
Total:	$79,898.00	802

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 01/07/2015	$79,898.00	802
Cumulative Approved:	$79,898.00	802

Work Assignment Manager Name: Britta Bierwagen (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8613 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-10

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Preparing Materials on Public
	Base Option Period Number 1	

Contractor: ICF Incorporated, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:
D. Analysis, Document & Issue Paper Preparation, E. Risk Assessment Support, G. Literature Search

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2015 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Charles Bevington (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-8814 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 1-10

TITLE: Preparing Materials on Public and Commercial Buildings (P&CBs) for Pb Rulemaking

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Specify Section & Paragraph SOW: Please select from the following: D. Analysis, Document & Issue Paper Preparation, E. Risk Assessment Support, G. Literature Search

PERIOD OF PERFORMANCE: *11/1/2014 to 10/31/14*

I. PURPOSE

The purpose of work assignment is to provide continued services to the U.S. Environmental Protection Agency's (EPA) (hereinafter EPA or Agency) Office of Pollution Prevention and Toxics (OPPT), in the completion of the Estimation of Health Effects from Exposure Scenarios that disturb Lead Based Paint from Exteriors and Interiors of Public and Commercial Buildings.

II. BACKGROUND

EPA is undertaking rulemakings intended to revise certain provisions of the Lead Renovation Repair and Painting (LRRP) Rule and to cover public and commercial buildings not covered by the LRRP rule. Under previous work assignments, the contractor provided support for many activities including the following:

- Developing an approach for estimating the residential dust hazard standards that would achieve each of four alternative targets for blood lead concentration in children under age 6, and for estimating the IQ change in children under age 6 associated with each alternative. This was reviewed by the SAB in July 2010
- Refining the approach for estimating the residential dust hazard standards that would achieve each of the three alternative targets for blood lead concentration in children under age 6, and for estimating the IQ change associated with each alternative. The contractor estimated blood lead concentrations in children under age 6 using methods based on specific epidemiology papers.
- Developing an approach for estimating the dust hazard standards for interior renovations in P&CBs that would achieve each of three alternative targets for blood lead concentration in children under age 6, and for estimating the IQ change in children under age 6 associated with each alternative dust hazard standard. The contractor developed an approach for estimating certain cardiovascular effects in adults for each alternative dust hazard standard.
- Refining the approach for estimating hazard standards in residences and P&CBs after a second review by the SAB in December 2010.
- Development of an Approach to estimate benefits from exterior renovations of P&CBs that contain lead paint. Blood lead estimates were estimated using the IEUBK model and IQ changes were estimated for young children. This Approach document was completed in 2012 but was not released because of a settlement agreement which combined exterior and interior renovations for P&CBs.
- Development of an Approach to estimate benefits from exterior and interior renovations of P&CBs that contain lead based paint. Blood and bone lead estimates were estimated using an updated version of the Leggett model and IQ changes were estimated for children 0-10 while cardiovascular disease mortality,

reduced kidney function, and low birth weight health outcomes were estimated for adults. This Approach document was completed and released on August 6, 2014.

The Approach and its supporting documents will be peer reviewed by a panel in January 2015. This work assignment will consist of a series of technical directions designed to refine the Approach to address peer review comments and to incorporate new data sources as they become available from a survey which will collect information on renovation activities in P&CBs.

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, that shows assigned personnel by task and the qualifications of the proposed personnel. This work assignment will require contractor staff to be thoroughly familiar with the IQ change analysis that was performed for the 2008 LRRP final rule. That rule and directions to its support materials may be found at http://www.epa.gov/lead/pubs/renovation.htm. Contractor staff with expertise in pharmacokinetic modeling of lead, biostatistics for lead, and computer modeling for lead are essential for this work assignment.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "*EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs* (QAPP)"; "*EPA Requirements for Quality Assurance Project Plans (QA/R-5)*"; and "Appendix A. *Guidance on Quality Assurance Project Plans for Secondary Research Data.*"

The QAPP shall be submitted simultaneously with the Work Plan for approval. The Contractor shall not perform any work on subsequent tasks under this WA until the Work Plan and QAPP are reviewed and approved. The contractor shall not perform any computer modeling work under this work assignment until the quality assurance statement is reviewed and approved by the WAM and the OPPT QA Manager.

Task 3: Incorporate Peer Review Feedback into the Approach

The Approach and its supporting documents will be peer reviewed by a panel in January 2015. The contractor shall plan to attend that meeting which will be held over a period of two days in Crystal City, VA. The contractor shall take summary level notes describing observations of peer review panel members and organize them by peer review question.

Task 4: Incorporate Survey Results or other information characterizing Renovation Activities into the Approach

The Agency is planning to undertake a survey in early 2015 to collect information on renovation activities conducted in P&CBs. Should the survey information not be available, alternative information will be provided to the contractor characterizing renovation activities in P&CBs from other data sources. The contractor shall update the modeling inputs and data sources file to reflect new information from the Survey.

Task 5: Update Modeling and Incorporate into Approach

The Approach and its supporting documents will need to be revised based on both peer review feedback and results from the Survey. Exposure scenarios modeled for the Approach may need to be refined. The contractor should assume that refinements will be needed in a number of areas including but not limited to: use and interpretation of alternative data sources to estimate input variables, use of alternative models or approaches to estimate outdoor or indoor environmental concentrations, use of alternative approaches to estimate intake rates such as dust ingestion in adults, use of different concentration-response functions for various health endpoints, refined consideration of time spent using different age groups, reclassification of model input variables from sampled to scenario and vice versa.

Under a previous work assignment, the contractor developed a data processing plan. The contractor shall work with EPA to scope any modelling updates and subsequent modeling outputs to ensure that this large amount of data can be processed and delivered to EPA within a period of no more than 3 weeks.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.(d), *.out, *opt, *.ssn]).

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan, and QAPP	20 days after award

Note: All days are calendar days.

By January 31, 2015, the contractor shall deliver to the WAM a final report for Task 3, as prescribed by the WAM.

By March 1, 2015, the contractor shall deliver to the WAM a final report for Task 4, as prescribed by the WAM.

By April 30, 2015, the contractor shall deliver to the WAM a draft report for Task 5, including the analyses that provide support to the benefits analysis, in a format to be specified based on the needs of the economics contractor which will be specified via written technical direction from the WAM.

During the month of May 2015, the contractor shall deliver to the WAM results of modeling for interior and exterior scenarios to incorporate into a revised Approach document to be used by the economists to develop their economics analysis in support of the proposed rulemaking.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO , WAM or CO

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):
Charles Bevington
OPPT-RAD AB2
Bevington.charles@epa.gov
202-564-8814

Alternate Work Assignment Manager (Alt WAM):
Ruth Hummel
OPPT-RAD AB3
Hummel.ruth@epa.gov
202-564-6055

Appendix A

Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

FOCUS: the work not only addresses the area of inquiry under consideration but also contributes to its understanding;
VERIFY: the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;
INTEGRITY: Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?
RIGOR: the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;
UTILITY: the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.
CLARITY: Is it written clearly and appropriately for the nature of the study?

Use the check list on the following page to evaluate the key studies.

DATA CHECKLIST FOR EVALUATING A STUDY

1.) Bibliographic identification of the study.

Study Identifiers:
Author(s):
Title:
Study Citation:
Storage location (e.g., library, facility archive, personal archive):

2.) Why is the study key to the particular project? (For example, is the study an example of new research or confirmation of previous work? Is the study's population larger or followed for a longer period of time than before, is the methodology better than other studies or corrective of problems in previous studies, or do the results provide new insight into the problem?)

3.) Summarize the study structure and methodology. What sampling techniques and statistical tests are used?

4.) Potential problem areas in the study; consider: study design, factors occurring within and outside of the study which may affect its validity, sampling errors, and any other perceived weaknesses.

5.) Do any data used from sources outside of the study seem reliable and generally free of measurement error? Discuss and give examples.

6.) Evaluate the study in terms of the appropriateness of the analytical methodology. In responding, consider the following questions:

Are research questions clearly stated; dependent and independent variables clearly defined?

Do the authors explain the type of data obtained from measures of the variables?

Are statistical methods adequately described; are they justified?

Is a source provided for the any statistical software used to analyze the data?

Is the purpose of the analysis clear?

Are any scoring systems described?

Are potential confounders adequately controlled for in the analysis?

Are analytic specifications of the variables consistent with the evaluation questions or hypotheses under study?

Is the unit of analysis specified clearly?

If statistical tests are used to determine comparability or difference, are p values provided; is the practical significance of these findings, as contrasted with the statistical significance, discussed?

7.) Evaluate the study's results. Consider the following questions:

Are study questions (objectives, hypotheses) clear?

Are all study questions answered?

Are negative findings presented?

Are missing data explained?

Are text and tables, figures, and graphs consistent?

8.) Evaluate the study's conclusions. Consider the following questions:

Are the conclusions based on the study's data in that findings are applied only to the sample that was included in the research?

When the authors compare their findings with those from another study, do the authors demonstrate the similarity of the two studies?

Does the author discuss limitations of design, sampling, data collection, etc.?

To what extent do the limitations affect one's confidence in the conclusions?

9.) How strong is the study, overall; relative to other similar studies? Do its weaknesses jeopardize its being a key study, or is it usable despite the reservations?

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-10

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2015	Pb renovation rule
	Base Option Period Number 1	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: D. Analysis, Document & Issue Paper Preparation, E

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2014 To 10/31/2015

Comments:
D. Analysis, Document & Issue Paper Preparation, E. Risk Assessment Support, G. Literature Search

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2015	$0.00	0
This Action:	$306,011.00	3,040
Total:	$306,011.00	3,040

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 11/03/2014	$306,011.00	3,040
Cumulative Approved:	$306,011.00	3,040

Work Assignment Manager Name: Charles Bevington (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-8814 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107